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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,391

11/12/2003

Gerald B. Pier

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

02/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,391	Applicant(s) PIER ET AL.	
	Examiner CHRISTIAN L. FRONDA	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 34, 40, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116 and 134-139 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71 and 139 is/are allowed.
- 6) ☒ Claim(s) 63, 69, 70 and 136-138 is/are rejected.
- 7) ☒ Claim(s) 134 and 135 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 10, 34, 40, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116, and 134-139 are pending in the application. Claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 stand withdrawn from consideration as drawn to a non-election invention.
2. Claims 63, 69-71, and 134-139 are under consideration in this Office Action
3. The rejection of claims 63, 69-71, and 134-139 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of the claim amendment filed 11/05/2008.
4. The previous grounds of rejection of claims 63, 69-71, and 134-139 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of the claim amendment filed 11/05/2008. However, because of the recitation of “region corresponding to”, new grounds of rejection are presented.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 63, 69, 70, and 136-138 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite for reciting the phrase “region corresponding to”. The instant specification does not provide teaching on how to precisely and accurately determine the exact “region corresponding to nucleotides 23-29 of SEQ ID NO: 2” and “region

corresponding to between and including nucleotides 24-28 of SEQ ID NO: 2” in the genus of nucleic acid molecules that hybridize under the recited stringent conditions to SEQ ID NO: 2. Dependent claims 69, 70, and 136-138 are also rejected because they do not correct the defect.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 63, 69, 70, and 136-138 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule an isolated nucleic acid molecule comprising SEQ ID NO: 1 or a full complement thereof; **does not** reasonably provide enablement for any other embodiment in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The arguments filed 11/05/2008 have been fully considered but are not persuasive for reasons of record as supplemented below.

The claims as amended now encompass a broad genus of nucleic acids that hybridize to SEQ ID NO: 2 under the recited stringent hybridization conditions where the nucleic acids now have the “region corresponding to nucleotides 23-29 of SEQ ID NO: 2” and the “region corresponding to between and including nucleotides 24-28 of SEQ ID NO: 2”.

However, the instant specification does not provide guidance, prediction, and working examples on how to precisely and accurately determine the exact “region corresponding to nucleotides 23-29 of SEQ ID NO: 2” and “region corresponding to between and including nucleotides 24-28 of SEQ ID NO: 2” in the genus of nucleic acid molecules that hybridize under

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the recited stringent conditions to SEQ ID NO: 2. Thus, one must perform an enormous amount of trial and error experimentation to search and screen for the claimed nucleic acids from any biological source or chemically synthesize the nucleic acids and determine if they can be used to enhance production of poly-N-acetyl glucosamine. General teaching regarding screening and searching for the claimed invention using the aggregation assays stated in the specification is not guidance for making the claimed invention.

Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Conclusion

9. Claim 71 and 139 are allowed.

10. Claims 134 and 135 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Primary Examiner

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